

Declaration of a compartment free of Infectious Salmon Anaemia (ISA) in Norway.

<i>Requirements/information needed</i>	<i>Information/further explanation and justification</i>
1. Identification of the programme	
1.1. Declaring Member State	Norway
1.2. Competent authority (address, fax, e-mail)	The Norwegian Food Safety Authority, Head office, Section for fish health and fish welfare, Felles postmottak, postboks 383, 2381 Brumunddal. postmottak@matilsynet.no
1.3. Reference of this document	Council Directive 2006/88/EC, Article 50, Annex V
1.4. Data sent to the Commission	13.03.2017
2. Type of communication	
2.1. <input checked="" type="checkbox"/> Declaration of disease-free status	
2.2. <input type="checkbox"/> Submission of application for disease-free-status	
3. National legislation¹	<p>Acts: The Food Act of 19 December 2003 No. 124</p> <p>Regulations:</p> <ul style="list-style-type: none"> • Regulations 17 June 2008 No. 819 on the placing on the market of aquaculture animals and product thereof, prevention and control of infectious diseases in aquatic animals. • Regulations 17 June 2008 No. 823 on the establishment and expansion of aquaculture establishments, pet shops etc. • Regulations 17 June 2008 No. 822 on operation of Aquaculture Establishments (Aquaculture Operation Regulations). • Regulations of 27 October 2007 No. 1254 on animal by-products not intended for human consumption.
4. Diseases	
4.1. Fish	<input type="checkbox"/> VHS <input type="checkbox"/> IHN <input checked="" type="checkbox"/> ISA <input type="checkbox"/> KHV
4.2. Molluscs	<input type="checkbox"/> infection with <i>Marteilia refringens</i> <input type="checkbox"/> infection with <i>Bonamia ostreae</i>
4.3. Crustaceans	White spot disease
5. Grounds for disease free-status	
5.1. <input type="checkbox"/> No susceptibles ²	
5.2. <input type="checkbox"/> Pathogen not viable ³	
5.3. <input type="checkbox"/> Historic free-status ⁴	

¹ National legislation in force applicable to the declaration of and application for disease-free status.

² Applicable if none of the species susceptible to the disease(s) in question is present in the Member State, zone or compartment, and where relevant in its water source.

³ Applicable if the pathogen is known not to be able to survive in the Member State, zone or compartment, and where relevant in its water source. Provide the scientific information supporting the inability of the pathogen to survive in the Member State, zone or compartment.

⁴ ~~Applicable if susceptible species are present, but where there has not been any observed occurrence of the disease for at least a period of 10 years before the date of declaration of application for the disease-free status; despite conditions that are conducive to its clinical expression, and if it complies *mutatis mutandis* with the requirements laid down in Part 1.1. of Annex V to Directive 2006/88/EC. This ground for disease-free status~~

5.4. x Targeted surveillance ⁵	<p>Description of the surveillance programme.</p> <p>Approval of establishments of aquaculture farms in Norway has been compulsory since 1985. The national legislation (regulation of June 2008 NO 819) concerning the placing on the market and imports of aquaculture animals for farming or restocking in Norway is in the accordance with the requirements of directive 2006/88/EC. Basic biosecurity measures have been in place continuously since 1990. The implementation of trade and imports conditions to prevent introduction of the diseases into Norway is effective.</p> <p>To maintain zones and compartments with ISA-free status the Norwegian Food Safety Authority carry out at least one inspection annually and take/arrange for necessary samples to be analysed according to Commission implementing decision (EU) 2015/1554 of September 11th 2015).</p> <p>If ISA is confirmed, the Norwegian Food Safety Authority will impose the control measures which are needed to eradicate the disease from the compartment and to prevent spread of the disease to other sites. Each zone/compartment would be placed under extended surveillance involving two official inspections annually, samples from at least 2 x 75 fish, risk based surveillance and sampling. Sampling will be performed by Norwegian Food Safety Authority in connection with inspections and by veterinarian and aqua medicine biologists performing the monthly inspections in the compartment.</p> <p>The National Reference Laboratory is the Norwegian Veterinary Institute. For details on the early detection system and diagnostic methods see section 6.5</p>
6. General information	
6.1. Competent authority ⁶	<p>The competent authority organizing and surveying health control for aquaculture industry in Norway is the Norwegian Food Safety Authority (NFSA).</p> <p>The NFSA has two administrative levels, the head office and five regional offices. The Norwegian Food safety Authorities has about 1300 employees. The 32 local offices carry out practically all of the active inspections. Having offices throughout the country means that the NFSA is close to both consumers and the relevant business.</p> <p>For more information about the NFSA please read the presentation in Annex 1.</p>
6.2. Organisation, supervision of all stakeholders involved in the programme to achieve disease free status ⁷	<p>The NFSA supervise all farms, aquatic animal health services and laboratories involved in the surveillance program and coordinate the measures taken to fulfil the requirements to achieve disease free status.</p>

~~must be declared of or applied for by 1 November 2008. Provide detailed information on the compliance with Part 1.1. of Annex V to Directive 2006/88/EC.~~

- ⁵ Applicable if targeted surveillance complying with Community requirements has been in place for at least a period of two years without the detection of the disease agent on farm, or in mollusc farming areas that rears any of the susceptible species.
- Where there are parts of the Member State, zone or compartment in which the number of farms or mollusc farming areas is limited, but in which there are wild populations of susceptible species, information on the targeted surveillance in those wild populations shall be given.
- Describe diagnostic methods and sampling schemes. When OIE or EU standards are applied, reference must be made to them. If not, describe them. Name the laboratories involved in the programme (National reference laboratory or designated laboratories).
- ⁶ A description shall be provided of the structure, competencies, duties and powers of the competent authority involved.
- ⁷ A description shall be provided of the competent authority in charge of the supervision and coordination of the programme and the different operators involved.

	<p>In addition to the surveillance programme all fresh water farms in Norway are obliged to be subject to a minimum of twelve health inspections by veterinarians or aqua medicine biologists (animal health professional) annually</p> <p>All sampling and supervision of the health situation in the compartment 13584 Tosbotn is carried out by veterinarian or aqua medicine biologist. All analyses are performed by laboratory accredited for ISA-virus analysis in accordance with OIE standards, usually Patogen Analyse AS.</p>
<p>6.3. An overview of the structure of the aquaculture industry in the area in question (disease-free Member State, zone or compartment) including types of production and species kept</p> <p>PCR flyttes til biosecurity?</p>	<p>Compartment details</p> <p>Compartment 13584 Tosbotn is a land based freshwater aquaculture farm in Brønnøy municipality in Nordland County. Owner is Marine Harvest Region North. The compartment is located at the end of Tosenfjorden, an arm of the Bindalsfjorden (see attached maps in Annex 2).</p> <p>Site 13584 Tosbotn is a closed mainly freshwater land based farm for smolt production that meets the requirements in Annex V part 2, point 4.2 of Directive 2006/88 to be free of ISA. There are no other freshwater farms in the entire water catchment area nearer than 30 km. This means that site 13584 Tosbotn represent a single epidemiologic unit not dependent of health status in surrounding waters. Nearest sea site activity is 9,5 km away.</p> <p>The site 13584 Tosbotn receive only salmon fry from ISA-free salmon fry producer 10265 Kongsmoelva within Marine Harvest brood stock system. The production from fry stage to completed smolt stage ready to put to sea, is performed in completely closed tanks. The smolt will be transferred out of the site through entirely closed pipes to wellboat.</p> <p>The compartment 13584 Tosbotn is mainly a freshwater site, but using disinfected seawater in end stage of smolt production. Intake of seawater from 80 meter depth 350 meter south of land base. The seawater is filtered before UV-disinfection (Bernouilly filter 200 micron). After filter the seawater is disinfected by use of UV unit. There are two independent UV units. One is continuously in use while the other is back up in case of weakened disinfecting efficacy or more severe failure to main UV unit. This way all used seawater is safely disinfected before entering tanks with salmon. Disinfecting efficacy is continuously monitored (intensity and mws).</p> <p>The Marine Harvest Company, owner of the site 13584 Tosbotn, has internal hygienic regulations for the staff. Special working outfits and equipment are not transported into the farm unless being cleaned and disinfected in forehand. Welfare parameters such as mortality, appetite and environmental indicators are continuously being registered.</p> <p>Fish health situation is monitored continuously by staff on the site and inspection by veterinarian or fish health biologist is performed at least once every month. Additional controls are performed in case of increased mortality or obvious change of fish behaviour.</p> <p>Sampling of fish is risk based mostly depending on gross pathology and lab analysis dominated by PCR screening and supplied with histology if necessary.</p> <p>The application for ISAV-free status is based on emptying, total cleaning and disinfection of all facilities (including all pipes and tanks), followed by more than 6 weeks of fallowing, before intake of new ISA free material. This is confirmed by representative from NFSA, please refer to Annex 3.</p> <p>The only species in the compartment will be Atlantic salmon.</p>
<p>6.4. The notification to the competent authority of the suspicion and confirmation of the disease(s) in question has been compulsory since when (date)?</p>	<p>According to the legislation The competent authority must be notified in case of suspicion and confirmation of the disease in question. All suspicions and diagnoses of ISA are handled according to the approved scheme for the withdrawal of all fish in Norwegian farms infected with infectious salmon anaemia (ISA) (cf. The EFTA Surveillance Authority' Decision No 226/04/COL of 9 September 2004).</p>

	<p>In the case of suspicion of fish being infected with ISA, an official investigation to confirm or rule out the presence of the disease will be carried out as quickly as possible, involving at least one inspection and one sampling of about 10 fish. ISA diagnostics are done at The Norwegian Veterinary Institute (reference lab) according to the methods outlined by the OIE. If ISA is confirmed the Norwegian Food Safety Authority will impose the control measures which are needed to eradicate the disease from the zone/compartments and to prevent spread of disease to other aquatic animals. Each zone/compartments that has been suspended from ISA-free areas based on trade or disease outbreaks, would be placed under extended surveillance involving at least one official inspection annually, samples from at least 2 x 30 fish, risk based surveillance and sampling.</p> <p>Monitoring is carried out by Norwegian Food Safety Authority and by fish health services as described in 5.4. In the event of suspicion or confirmation of ISA within ISA-free areas, trade with susceptible species and vector species to other areas with a higher health status for ISA will immediately be suspended in accordance with Article 53 of Directive 2006/88/EC and the ISA-free status will be withdrawn.</p> <p>The Norwegian Food Safety Authority is responsible for the control and supervision of the actions taken in case of a disease outbreak and will supervise the cleaning, disinfection and fallowing of the facility, risk-based surveillance and regular inspections.</p>
<p>6.5. Early detection system in place throughout the Member States, enabling the competent authority to undertake effective disease investigation and reporting since when (date)?⁸</p>	<p>An early detection system and compulsory notification system for all listed diseases, including exotic diseases, has existed since 1990 (cf. Act of 22 June 1990 No. 44).</p> <p>Approval of establishments of aquaculture farms has been compulsory in Norway since 1985. The national legislation (Regulations of 17 June 2008 No. 819) on the placing on the market and imports of aquaculture animals for farming or restocking, is in the accordance with the requirements of Directive 2006/88/EC.</p> <p>Basic biosecurity measures have been in place continuously since 1990 in the Norwegian legislation. The implementation of requirements for the placing on the market and import to prevent introduction of the disease into Norway is effective.</p> <p>To maintain zones/compartments with ISA-free status Norwegian Food Safety Authority carry out at least one inspection annually and take/arrange to have taken samples from 30 fish.</p> <p>There is a broad awareness among the personnel employed in aquaculture businesses or involved in the processing of aquaculture animals of any signs consistent with the presence of a disease, as they are obliged to keep daily records of the health status and to have the following competence:</p> <ul style="list-style-type: none"> (i) Anyone participating in aquaculture activities covered by Regulations 17 June 2008 No. 819 is obliged to have the necessary professional knowledge to perform those activities. The person responsible for the daily operation of aquaculture establishments must be educated in aquaculture business including knowledge about management, animal health and welfare. (ii) The competence must be documented through practical and theoretical training.

⁸ The early detection systems shall in particular ensure the rapid recognition of any clinical signs consistent with the suspicion of a disease, emerging disease, or unexplained mortality in farms or mollusc farming areas, and in the wild, and the rapid communication of the event to the competent authority with the aim to activating diagnostic investigation with minimum delay. The early detection system shall include at least the following:

- (a) broad awareness, among the personnel employed in aquaculture businesses or involved in the processing of aquaculture animals, of any signs consistent with the presence of a disease, and training of veterinarians of aquatic animals health specialists in detecting and reporting unusual disease occurrence;
- (b) veterinarians or aquatic animal health specialists trained in recognising and reporting suspicious disease occurrence;
- (c) access by the competent authority to laboratories with the facilities for diagnosing and differentiating listed and emerging diseases.

	<p>All fresh water and brood stock farms in Norway are obliged to be subject to a minimum of 12 health inspections by veterinarians or aqua medicine biologists (animal health professional) annually.</p> <p>The NFSA has full access to laboratories with the facilities for diagnosing and differentiating all listed diseases.</p> <p>At a minimum an operating journal at the production level must contain updated information on;</p> <ul style="list-style-type: none"> a) Stocking of fish: date, species, number of fish, cohort and origination, b) Slaughtered quantity: date, species, number of fish, slaughter weight and slaughter condition, c) Removal of live fish: date, species and quantity. If fish are removed a journal entry shall be made of the aquaculture establishment to which the fish have been moved, d) Real volume, e) Health and welfare status of the fish: number of health checks, number of autopsied fish, sampling, examinations, diagnosis, injuries, treatments and known or probable causes of injuries and production diseases, f) Mortalities g) Relevant parameters for water quality and water quality measures, h) Attacks by predators, algae or jellyfish and other measures taken. <p>Data regarding b), c) and f) must be reported monthly to the competent authority.</p>
<p>6.6. Source of aquaculture animals of species susceptible to the disease in question entering in the Member State, zone or compartments for farming.</p>	<p>The entering of species susceptible to ISA into the ISA-free compartment is only allowed from other ISA-free Member States, zones or compartments. All consignments must be accompanied by a health certificate from the place of origin declaring the source to be disease free of ISA.</p> <p>Only ISA-free salmon fry from ISA-free salmon fry producers are allowed to be imported to the compartment 13584 Tosbotn. The only species in the compartment will be Atlantic salmon.</p>
<p>6.7. Guidelines on good hygiene practice⁹</p>	<p>Regulations 17 June 2008 No. 819 relating to the placing on the market of aquaculture animals and products thereof, prevention and control of infectious diseases in aquatic animals, give guidelines on hygiene practices for handling of fish with suspected or diagnosed animal disease and on the fish farmers own supervision, including good hygiene practices in farms.</p> <p>Handling of dead fish is done in accordance with;</p> <ul style="list-style-type: none"> - Regulations 17 June 2008 No. 822 Regulations relating to Operation of Aquaculture Establishments (Aquaculture Operation Regulations) - Regulations of 27 October 2007 No. 1254 on animal by-products not intended for human consumption.
<p>7. Area covered</p>	
<p>7.1. Member State</p>	

⁹ A description shall be provided in accordance with Article 9 of Directive 2006/88/EC

7.2. <input type="checkbox"/> Zone (entire water catchment area) ¹⁰		
7.3. <input type="checkbox"/> Zone (part of water catchment area) ¹¹ Identify and describe the artificial or natural barrier that delimits the zone and justify its capability to prevent the upward migration of aquatic animals from the lower stretches of the water catchment area.		
7.4. <input type="checkbox"/> Zone (more than one water catchment area) ¹²		
7.5. <input checked="" type="checkbox"/> Compartment independent of the surrounding health status ¹³		
<p>The compartment 13584 Tosbotn has internal hygienic procedures for the staff, visitors and equipment entering the compartment. If equipment is taken in to the compartment it has to be cleaned and disinfected prior to entrance, according to Marine Harvest internal procedures in accordance with the Norwegian Food Safety Authority regulations.</p> <p>Welfare parameters such as mortality, environmental indicators like temperature, pH, oxygen and CO₂ levels are continuously monitored.</p> <p>The fish health service conducts at least one health control every month and additional controls in case of increased mortality or observed changed behavior. The sampling is risk based depending on gross pathology. The laboratory analyses are dominated by PCR –analyses (Patogen Analyse AS) and histology (Veterinary Institute).</p>		
Identify and describe for each farm the water supply ¹⁴	Well, borehole or spring Water treatment plant inactivating the relevant pathogen ¹⁵	<p>The compartment includes the landbase itself and 1) the freshwater source, water intake from river Leiråa. See Annex 2 with maps describing this water source and 2) the seawater intake to compartment (80 meters depth, 350 meters south of landbase itself). There are no other aquaculture activities in connection with the freshwater source nearer than 30 km and no other seawater aquaculture activity nearer than 9 km.</p> <p>The site 13584 Tosbotn only uses freshwater in first and main part of smolt production after receiving salmon fry from ISA-free fry producer. In the end stage of smolt production the site also use UV-disinfected seawater.</p> <p>River Leiråa arising from Leiråvatnet is the only freshwater source used in the compartment.</p> <p>All seawater used in the production is disinfected through heavy UV units.</p> <p>Disinfecting effect of UV-unit is monitored.</p>

¹⁰ An entire water catchment area from its sources to its estuary.

¹¹ Part of a water catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of aquatic animals from the lower stretches of the water catchment area.

¹² More than one water catchment area, including their estuaries, due to the epidemiological link between the catchment areas through the estuary.

¹³ Compartments comprising one or more farms or mollusc farming areas where the health status regarding a specific disease is independent of the health status regarding that disease of surrounding natural waters.

¹⁴ A compartment which is independent of the health status of surrounding waters, shall be supplied with water:

(a) through a water treatment plant inactivating the relevant pathogen in order to reduce the risk of the introduction of the disease to an acceptable level; or

(b) directly from a well, a borehole or a spring. Where such water supply is situated outside the premises of the farm, the water shall be supplied directly to the farm, and be channelled through a pipe.

¹⁵ Provide technical information to demonstrate that the relevant pathogen is inactivated in order to reduce the risk of the introduction of the disease to an acceptable level.

Identify and describe for each farm natural or artificial barriers and justify its capability to prevent that aquatic animals enter each farm in a compartment from the surrounding watercourses.	There is a high dam located downwards from the water intake that makes it impossible for advance of anadromic fish to the freshwater source (Annex 4).
Identify and describe for each farm the protection against flooding and infiltration of water from the surrounding	The water pipes leading the water to the site from freshwater source and from seawater intake are totally closed to the surroundings on their way to the plant. The bottom of the tanks on the site are at the lowest more than 1 meter above maximum sea flood level. There is no possibility that sea water or freshwater from outside can reach the facility.
7.6. Compartment dependent on the surrounding health status¹⁶	
One epidemiological unit due to geographical localisation and distance from other farms/farming areas ¹⁷	
All farms comprising the compartment fall within a common biosecurity system. Describe the common biosecurity system. ¹⁸	
<input type="checkbox"/> Any additional requirements ¹⁹	
8. Geographical demarcation²⁰	
8.1. Farms or mollusc farming areas covered (registration numbers and geographical situation)	Marine Harvest compartment 13584 Tosbotn. See maps in Annex 2. Geographical position: To the North: 65 degrees 19.462` To the East : 12 degrees 55.304`
8.2. <input type="checkbox"/> Non-free buffer zone ²¹	Geographical demarcation ²⁶
	Farms or mollusc farming areas covered (registration numbers, geographical situation and health status ²²)
	Type of health surveillance
8.3. <input type="checkbox"/> Non-free zones or compartments ²³	Geographical demarcation ²⁶
	Farms or mollusc farming areas covered (registration

- ¹⁶ Compartments comprising one or more farms or mollusc farming areas where the health status regarding a specific disease is dependent on the health status of surrounding natural waters regarding that disease.
- ¹⁷ A description shall be provided of the geographical localisation and the distance from other farms/farming areas that makes it possible to consider the compartment as one epidemiological unit.
- ¹⁸ A description shall be provided of the common biosecurity system.
- ¹⁹ Each farm or mollusc farming area in a compartment which is dependent on the health status of surrounding waters shall be subject to additional measures imposed by the competent authority, when considered necessary to prevent the introduction of diseases. Such measures may include the establishment of a buffer zone around the compartment in which a monitoring programme is carried out, and the establishment of additional protection against the intrusion of possible pathogen carriers or vectors.
- ²⁰ The geographical demarcation shall be clearly described and identified on a map, which must be attached as an Annex to the declaration/application. Any substantial modification in the geographical demarcation of the zone or compartment to be declared free must be subjected to a new application.
- ²¹ In connection with a zone or a compartment dependent on the health status of surrounding waters, a buffer zone in which a monitoring programme is carried out shall be established, as appropriate. The demarcation of the buffer zones shall be such that it protects the disease-free zone from passive introduction of the disease. (Part II.1.5 of Annex V to Directive 2006/88/EC).
- ²² Health status in accordance with Part A of Annex III to Directive 2006/88/EC.
- ²³ Relevant in cases of declaration of disease-free Member States, where minor areas of the Member State are not considered disease-free.

	numbers geographical situation and health status ²²⁾	
8.4. <input type="checkbox"/> Extension of disease-free zone to other Member States ²⁴	Geographical demarcation ²⁶	
8.5. <input type="checkbox"/> Existing disease-free zones/compartments in the vicinity.	Geographical demarcation ²⁶	
	Farms or mollusc farming areas covered (registration numbers and geographical situation)	
9. Farms or mollusc farming areas which commence or recommence their activities²⁵		
9.1. New farm		
9.2 <input checked="" type="checkbox"/> Recommencing farm	Health history of farm known to Competent authority	<p>Compartment 13584 Tosbotn has never had history of ISA-virus restrictions. Marine Harvest department 13584 Tosbotn is as described a single, closed farm for the ongrowing of salmon fry to the smolt stage for delivering to sea sites within the company.</p> <p>The application for ISAV –free status is based on emptying, total cleaning and disinfection of all facilities, followed by more than six weeks following period. See attached washing and disinfection plans, Annex 5. Washing and disinfection performed on the plant is confirmed by representative from NFSA (Annex 3).</p>
	<input type="checkbox"/> Not subject to animal health measures in respect of listed diseases	The site 13584 Tosbotn has never had restrictions related to detection of ISA virus.
	<input type="checkbox"/> Farm cleaned, disinfected and, as necessary, fallowed	The site 13584 Tosbotn was emptied, cleaned and disinfected completely in two rounds followed by more than six weeks following period. The total emptying, cleaning, disinfection and fallowing period is confirmed by representative from NFSA.

²⁴ Where a zone extends to more than one Member State, it may not be declared a disease-free zone unless the conditions set out in points 1.3, 1.4, and 1.5 of Part II of Annex V to Directive 2006/88/EC apply to all areas of that zone. In that case both Member States concerned shall apply for approval for the part of the zone situated in their territory.

²⁵ In accordance with Part II.4 of Annex V to Directive 2006/88/EC